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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/906,365	08/05/97	BHAT	R 0646/0D205

EXAMINER

HM11/0903

BAST, N

DARBY AND DARBY
805 THIRD AVENUE
NEW YORK NY 10022

ART UNIT	PAPER NUMBER
1646	4

DATE MAILED: 09/03/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 30 days ~~month(s), or thirty days~~, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-23 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-23 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

–SEE OFFICE ACTION ON THE FOLLOWING PAGES–

★ U.S. GPO: 1998-421-632/40208

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1646.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant must comply with the sequence rules, 37 CFR 1.821 - 1.825 within the statutory period set for response to this office action. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for response beyond the SIX MONTH statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, drawn to the polynucleotide sequence comprising SEQ ID NO:1 or encoding the polypeptide of SEQ ID NO:2, vectors encoding, cells containing the afore mentioned expression vectors and a method of production and recovery of said polypeptide, classified in class 536 , subclass 23.1, for example .

II. Claims 17 and 18, drawn to a purified polypeptide depicted in SEQ ID NO:2, function-conservative variant thereof, classified in class 530, subclass 350/300, for example.

III. Claims 19-22, drawn to a method for identifying hERβ-interactive compounds, classified in class 435, subclass 7.1 for example.

IV. Claim 23, drawn to antibody that recognizes hERβ, classified in class 530, subclass 387.9, for example.

The inventions are distinct, each from the other because of the following reasons:

The proteins of Invention II are related to the nucleic acids of Invention I by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in claim 15. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source.

Further, the DNA may be used for the processes other than the production of the protein, such as nucleic acid hybridization.

The methods of Inventions I are related to the proteins of Invention II as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed may be isolated from its natural source or made by chemical peptide synthesis.

The proteins of Invention II are related to antibodies of Invention IV by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementary of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the cognate receptor of the protein, or in assays for the identification of agonists of the receptor protein.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed

can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins may be used for the production of antibodies of Invention IV.

The methods of Invention III are distinct and separate from the nucleic acids and methods of Invention I. The methods of Inventions I and III are distinct because they are independent, using separate method steps, active agents and having different effects. The products of Inventions I are distinct from the method of Invention III wherein the products of Invention I can neither be used in nor made by the methods of Invention III.

The antibody of Invention IV is distinct and separate from the nucleic acids and methods of Invention I. The antibody of Invention IV is distinct from the method of Inventions I wherein the antibody can neither be used in nor made by the methods of Invention I. The nucleic acid of Invention I is structurally and functionally different from the antibody of Invention IV.

The methods of Invention III are distinct and separate from the antibody of Invention IV. wherein the antibody of Invention IV can neither be used in nor made by the methods of Invention III.

A search of the art for Inventions I-IV would not be co-extensive with each other. Because the searches required for these inventions are not co-extensive an examination of the materially different, patentably distinct inventions in a single application would constitute a serious burden on the examiner.

An election to prosecute one of the groups listed I-IV must be made. Affirmation of this election must be made by applicant in responding to this Office action.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi
1646
28 August, 1998

LILA FEISEE
SUPERVISORY PATENT EXAMINER
GROUP 1800/600